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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,728	07/03/2003	Jeffrey Robbins	CHM02-GN053	8201

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EXAMINER

MONTANARI, DAVID A

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/613,728	ROBBINS, JEFFREY	
	<b>Examiner</b>	<b>Art Unit</b>	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

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## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 drawn to a isolated nucleic acid having a sequence set forth in SEQ ID NO: 1, an expression cassette comprising the nucleic acid of SEQ ID NO:1, a host cell comprising SEQ ID NO: 1 and a nucleic acid having at least 95% identity with SEQ ID NO: 1, classified in class 536, subclass 23.1.
- II. Claims 16-24 drawn to a transgenic mouse, rabbit, dog, pig, goat, monkey, chimpanzee, or cow comprising a nucleotide sequence set forth in SEQ ID NO: 1, or said transgenic animals comprising a nucleotide sequence that is at least 95% identical to SEQ ID NO: 1, classified in class 800, subclass 8.
- III. Claims 22-28, and 37, drawn to a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of identifying anti-cardiopathic compounds using said mouse, classified in class 800, subclass 18.
- IV. Claims 22-26, 29-30, and 37 drawn to a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a

nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of identifying anti-cardiopathic compounds using said mouse, classified in class 800, subclass 18.

- V. Claims 22-28, and 31-36 drawn to a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of altering expression of a nucleotide sequence of interest using said mouse, classified in class 800, subclass 18.
- VI. Claims 22-26, 29-36 drawn to a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of altering expression of a nucleotide sequence of interest using said mouse, classified in class 800, subclass 18.

Inventions I and II are distinct because they are of separate uses. Invention I is an isolated nucleic acid set forth in SEQ ID NO: 1, an isolated nucleic acid having at least 95% identity with SEQ ID NO: 1, and a host cell, vector, and expression cassette comprising either said nucleic acids. Invention II is a transgenic animal comprising nucleotide sequence of interest operably

linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO:

1. The use of the transformed cell of Invention I comprising said nucleic acids can be used to examine expression of said nucleic acids *in vitro* and is of a separate use from the transgenic mouse of Invention II.

Inventions I and III are distinct because they are of separate uses. Invention I is an isolated nucleic acid set forth in SEQ ID NO: 1, an isolated nucleic acid having at least 95% identity with SEQ ID NO: 1, and a host cell, vector, and expression cassette comprising either said nucleic acids. Invention III is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The use of the transformed cell of Invention I comprising said nucleic acids can be used to examine expression of said nucleic acids *in vitro* and is of a separate use from the transgenic mouse of Invention III.

Inventions I and IV are distinct because they are of separate uses. Invention I is an isolated nucleic acid set forth in SEQ ID NO: 1, an isolated nucleic acid having at least 95% identity with SEQ ID NO: 1, and a host cell, vector, and expression cassette comprising either said nucleic acids. Invention IV is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The use of the transformed cell

of Invention I comprising said nucleic acids can be used to examine expression of said nucleic acids *in vitro* and is of a separate use from the transgenic mouse of Invention IV.

Inventions I and V are distinct because they are of separate uses. Invention I is an isolated nucleic acid set forth in SEQ ID NO: 1, an isolated nucleic acid having at least 95% identity with SEQ ID NO: 1, and a host cell, vector, and expression cassette comprising either said nucleic acids. Invention V is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The use of the transformed cell of Invention I comprising said nucleic acids can be used to examine expression of said nucleic acids *in vitro* and is of a separate use from the transgenic mouse of Invention V.

Inventions I and VI are distinct because they are of separate uses. Invention I is an isolated nucleic acid set forth in SEQ ID NO: 1, an isolated nucleic acid having at least 95% identity with SEQ ID NO: 1, and a host cell, vector, and expression cassette comprising either said nucleic acids. Invention VI is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The use of the transformed cell of Invention I comprising said nucleic acids can be used to examine expression of said nucleic acids *in vitro* and is of a separate use from the transgenic mouse of Invention VI.

Inventions II and III are distinct. Invention II is a transgenic animal comprising a nucleotide sequence of interest operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1. Invention III is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The transgenic animal of Invention II may comprise a nucleotide sequence of interest other than sequences of SEQ ID NO: 5 or 6 of the transgenic mouse of Invention III, and therefore may have a different phenotype.

Inventions II and IV are distinct. Invention II is a transgenic animal comprising a nucleotide sequence of interest operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1. Invention IV is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The transgenic animal of Invention II may comprise a nucleotide sequence of interest other than sequences of SEQ ID NO: 7 or 8 of the transgenic mouse of Invention IV, and therefore may have a different phenotype.

Inventions II and V are distinct. Invention II is a transgenic animal comprising a nucleotide sequence of interest operably linked to SEQ ID NO: 1 or a nucleotide sequence

having at least 95% identity with SEQ ID NO: 1. Invention V is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse.

The transgenic animal of Invention II may comprise a nucleotide sequence of interest other than sequences of SEQ ID NO: 5 or 6 of the transgenic mouse of Invention V, and therefore may have a different phenotype.

Inventions II and VI are distinct. Invention II is a transgenic animal comprising a nucleotide sequence of interest operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1. Invention VI is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse.

The transgenic animal of Invention II may comprise a nucleotide sequence of interest other than sequences of SEQ ID NO: 7 or 8 of the transgenic mouse of Invention VI, and therefore may have a different phenotype.

Inventions III and IV are distinct. Invention III is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide



sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. Invention IV is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The transgenic mouse of Invention III is genetically different from the transgenic mouse of Invention IV and therefore has a different phenotype.

Inventions III and V are distinct because they are of separate uses. Invention III is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. Invention V is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The methods of using the mouse of Invention III is materially different and of a separate use of the method to use the mouse of Invention V.

Inventions III and VI are distinct. Invention III is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95%

identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse.

Invention VI is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The transgenic mouse of Invention III is genetically different from the transgenic mouse of Invention VI and therefore has a different phenotype.

Inventions IV and V are distinct. Invention IV is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. Invention V is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The transgenic mouse of Invention IV is genetically different from the transgenic mouse of Invention V and therefore has a different phenotype.

Inventions IV and VI are distinct because they are of separate uses. Invention IV is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. Invention VI is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The methods of using the mouse of Invention IV is materially different and of a separate use of the method to use the mouse of Invention VI.

Inventions V and VI are distinct because they are of separate uses. Invention V is a transgenic mouse comprising SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 5 or 6 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. Invention VI is a transgenic mouse comprising SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, a transgenic mouse comprising a nucleotide sequence having at least 95% identity with SEQ ID NO: 7 or 8 operably linked to SEQ ID NO: 1 or a nucleotide sequence having at least 95% identity with SEQ ID NO: 1, and a method of using the mouse. The methods

of using the mouse of Invention V is materially different and of a separate use of the method to using the mouse of Invention VI.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required is different among each group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 1-571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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